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Richard D. Gresham

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EXAMINER

MCEVOY, THOMAS M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,914	Applicant(s) GRESHAM, RICHARD D.	
	Examiner THOMAS MCEVOY	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-26 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-26 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently claims 1, 2, 6-26 and 30-33 are pending and considered below. Claims 3-5 and 27-29 have been cancelled.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 and 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bulow et al. (US 5,665,073).

Regarding claims 1, 2 and 13, Bulow et al. disclose a surgical instrument comprising: a body portion, 32/36, 42/46, and/or 52/56; a tool member, 38, 48 and/or 58, supported on the distal end of the body portion; and a liquid impermeable elongated cover 12 (col. 5, lines 30-31) supported about the body portion of the instrument, the elongated cover being formed from a collapsible material and having a substantially tubular configuration having open proximal and distal ends, the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly, wherein when the elongated cover is in the first position the distal end of the

elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position (the cover can be draped and secured via 11 at any position along the surgical instrument). Guide members 72 and 73 can be considered as a cover deployment device which are between the cover and body portion(s) and which are in releasable engagement with the cover. When members 18 and 19 are released as in Figure 1 and the drawstring 11 is secured to the body portion adjacent the tool assemblies (which would be a reasonable configuration for this apparatus), the cover deployment device could be advanced along the body portion to move the cover from the first position to the second position. Regarding claims 6-8 the cover deployment sleeve half-sections 72/73 are movable to move the cover from the first position to the second position while being urged together by o-ring 11 or cover 12. Regarding claim 9, the sleeve includes a proximally located annular ring 76/77 dimensioned to facilitate movement of the sleeve between the retracted and advanced positions. Regarding claim 10, the first sleeve half-section includes at least one projection, 78 or 79 (Figure 3), and the second sleeve half-section includes at least one slot (the curved interior of 72 or 73). The projection can slide into the slot to maintain alignment between the first and second half-sections when the half-sections move outwardly (slide longitudinally relative to each other when stacked) with respect to each other. Regarding claim 11, movement of the cover deployment device from a retracted position to an advanced position can be used to invert the cover over the tool member. Regarding claim 12, the cover deployment device includes a distal

engagement member 78/79, a proximal guide portion 76/77 and a central body portion 74/75 interconnecting the engagement member and the guide portion. Regarding claims 14-16, a closure drawstring, 18 or 19, can close the proximal end of the cover after it has moved over the tool member. Regarding claim 17 the distal end of the cover is removably fastened to the surgical instrument by 11.

4. Claims 1, 2, 11 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Jespersen (US 2003/0139767).

Regarding claims 1, 11 and 13, Jespersen disclose a surgical instrument comprising: a body portion 32; a tool assembly 34/36 supported on the distal end of the body portion; and an elongated cover 12 supported about the body portion of the instrument, the elongated cover being formed from a collapsible material and having a substantially tubular configuration (Figure 6) having open proximal and distal ends (Figure 5A), the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly (Figure 7), wherein when the elongated cover is in the first position the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly (Figure 5A) such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position (Figure 7); and a cover deployment device at least partially disposed about the body portion, between the body portion and the cover (forceps 44, Figure 7; the forceps during normal use would engage the cover at a variety of positions, including positions which are 'about the body portion'; a portion of

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the cover deployment device could be placed between the cover and body in order to grasp the cover from its proximal and when undeployed), the cover deployment device in releasable engagement with the cover. Regarding claim 2, the cover can be liquid impermeable (paragraph 0034). Regarding claims 14-16, the cover contains an elastic band or drawstring 52/50 for closing the proximal end of the cover after it has moved over the tool assembly (paragraph 0022; paragraph 00042). Regarding claim 17, the distal end of the cover is movably fastened to the surgical instrument (Figure 5A).

5. Claims 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (US 5,318,221).

Regarding claims 30-33, Green et al. disclose a surgical instrument comprising: an elongated body portion 406/329; a tool assembly 334/336 (and other associated parts) supported on a distal end of the elongated body portion (member 334 is secured between member 329 and member 324 via pins 444, therefore member 329 helps support the tool assembly), the tool assembly including an anvil assembly and a shell assembly (Figure 17), the shell assembly having a plurality of surgical staples (col. 14, lines 4-5); an elongated cover 327 having a distal end fastened about the elongated body portion at a location adjacent a proximal end of the tool assembly (col. 14, lines 10-17; Figure 17). The cover is movable from a first proximal position to a second position to cover the stationary shell assembly (col. 14, lines 10-17). A cover deployment member 404 is movably positioned about the elongated body portion (Figure 17) between the elongated body portion and the cover, the cover deployment being slidable in a distal direction along the body portion (406/329 runs through 404) to

move the cover to the second position because it is attached to 327. The cover deployment member is a sleeve and is releasably attached to the cover by tabs 458 (Figure 22). In an alternate interpretation for claims 30-33, member 125/126 could be the cover deployment device for cover 127. Member 125 is positioned about and slidable along body 124 (Figure 5A) and a portion of member 125 is between body 124 and cover 127 (Figure 1; at 125).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulow et al. (US 5,665,073) in view of Williamson et al. (US 6,024,741).

Regarding claims 18-20, Bulow et al. disclose the device as disclosed above, and further disclose that the device is intended to protect the conduits of multiple surgical instruments (col. 5, lines 55-59), but do not disclose that it is usable with a linear/circular stapler or ultrasonic dissector. Williamson et al. disclose an ultrasonic cutter (col. 2, lines 1-11) circular/linear stapler (col. 3, lines 22-39) which has conduits, 30 or 19a-d. It would be obvious to one of ordinary skill in the art to combine the device of Bulow et al. with the instrument of Williamson et al. in order to protect and maintain the sterility of the conduits.

8. Claims 21, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jespersen (US 2003/0139767).

Regarding claim 21, Jespersen discloses a method of performing a surgical procedure comprising the following steps: providing a surgical instrument including a body portion 31, a tool assembly 34/36, a cover deployment device 44 and a cover 12 positioned about the cover deployment device, a distal end of the cover being secured about the instrument adjacent a proximal end (Figure 5A) of the tool assembly such that the cover is movable from a first position wherein the tool assembly is uncovered (Figure 5A) to a second position wherein the tool member is at least partially covered (as in Figure 7; paragraph 0044). Jespersen fails to specifically disclose placing the cover deployment device on the body portion. However, it would have been obvious to one of ordinary skill in the art to have contacted the cover deployment device with the body portion in order to grasp the proximal end of the cover, where it would be obvious to one of ordinary skill in the art to use graspers with bodies sufficiently long enough so that the proximal end of the cover would rest on some portion of the body when undeployed given the enumerable body lengths for graspers that could be used with the cover and the enumerable lengths that the cover could be constructed with in order to be sufficiently sized for the great variety of surgical capturing tasks. It is not clear whether Jespersen disclosed advancing the cover deployment device along the body in order to invert the cover. However, it would have been obvious to one of ordinary skill in the art to have used the cover deployment device to pull or push the cover to the inverted state given the great variety of angles which laproscopic instruments are

constrained to interact in during a surgical procedure. Certainly, situations would arise where the space constraints are such that one of ordinary skill in the art would need to grasp the cover from the proximal end and push the cover to the inverted state; and therefore push/advance the cover deployment device along the body portion.

Jespersen further discloses: positioning the surgical instrument adjacent a surgical site and performing a surgical operation on desired tissue (Figure 5A); moving the cover from the first position to the second position by inverting the cover at least partially over the tool assembly; (as in Figure 7; paragraph 0044) and subsequently removing the surgical instrument from the surgical site (paragraph 0041) while maintaining the cover at least partially over the tool assembly (paragraph 0023; paragraph 0044). Regarding claims 25 and 26, the surgical instrument includes a closure drawstring 52, and the method further includes the step of actuating the closure drawstring to close the cover at a location distally of the tool member (paragraph 0042).

9. Claims 18-20, 22-24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jespersen (US 2003/0139767) in view of Williamson et al. (US 6,024,741).

Regarding claims 18-20 and 22-24, Jespersen discloses the device as described above which is intended to be used with a grasping instrument but fails to disclose that the grasping instrument is a stapler or ultrasonic dissector. Williamson et al. disclose an ultrasonic cutter (col. 2, lines 1-11) and circular/linear stapler (col. 3, lines 22-39) and grasper (grasping elements 32 and 34). It would be obvious to one of ordinary skill in the art to combine the device of Jespersen with the instrument of Williamson et al. in

order to contain and remove grasped/cut tissue. Regarding claim 30, Williamson et al. disclose a stationary shell assembly 32/34 and body 30 as claimed. The cover of Jespersen would function with the stapler/grasper of Williamson et al. as depicted in Figures 5A and 7 of Jespersen. The cover deployment device 44 of Jespersen can be slid along the body of the stapler/grasper in order to invert the cover. The cover deployment device of Jespersen could be positioned about the body and a portion of the deployment device would need to go between the cover and the body in order to grasp the cover.

Response to Arguments

10. Applicant's arguments filed May 19th 2009 have been fully considered but are not persuasive. Applicant has argued that the cover deployment device of Bulow et al. is secured to the cover so the cover cannot be inverted over the tool assembly. Examiner respectfully disagrees. In use, the cover deployment device is not directly secured to the cover in any fashion that would prevent it from being inverted. Applicant has made statements in the first paragraph of p. 13 regarding the difficulty in using the guide 70 of Bulow et al. to invert the cover. Examiner has referred to members 72 and 73 as the cover deployment device. Since member 70 is not bonded to members 72 or 73 it could be slid off members 72 and 73 while the cover is being inverted. Applicant has effectively argued on p. 17 that the cover of Green et al. does not cover the stationary shell assembly as evidenced by Figure 15B. Examiner believes that at least in one depiction, Figure 11, 134B would be covered by the cover. The remainder of

Applicant's arguments have either been addressed in the above rejections or in the previous non-final Office Action of record.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/15/09